Docket No.: 080623-0349 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	:	Customer Number: 41552
VANDERVEEN, TIMOTHY W., et al.	:	Confirmation Number: 9475
Application No.: 10/750,345	:	Tech Center Art Unit: 3767
Filed: December 31, 2003	:	Examiner: Deanna K. Hall

For: MEDICATION SAFETY ENHANCEMENT FOR SECONDARY INFUSION

TRANSMITTAL OF APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
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I hereby certify that this correspondence is being electronically-transmitted to the United States Patent and Trademark Office on **March 9, 2009.**
/Kimila Carraway/
_____
Kimila Carraway

Sir:

Submitted herewith is Appellants' Appeal Brief in support of the Notice of Appeal filed October 9, 2008. Please charge the Appeal Brief fee of $540.00 to Deposit Account 502624.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. 1.17 §§ and 41.20, and in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed October 9, 2008, wherein Appellants appeal from the Examiner's final rejection of Claims 1-19.

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I. REAL PARTY IN INTEREST

The real party in interest is Cardinal Health 303, Inc. by way of the assignment recorded on January 25, 2006 at Reel 017063, Frame 0111.

II. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals and interferences.

III. STATUS OF CLAIMS

Claims 1-11 and 16-19 are pending in this application. Claims 1-11 and 16-19 have been finally rejected. It is from the final rejection of Claims 1-11 and 16-19 that this appeal is taken. Claims 1-11 and 16-19 are copied in the Claims Appendix to this Appeal Brief.

IV. STATUS OF AMENDMENTS

Arguments presented in the Amendment filed on August 21, 2008, in response to final Office Action have been considered by the Examiner, but failed to place the application in condition for allowance. The amendments to Claims 12 and 14 in the Amendment were not entered. Consequently, in the Amendment After Final filed herewith, Applicants have canceled Claims 12 and Claims 13-15 which depend therefrom in order to proceed with the process of appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to determining a fault condition in an infusion system. According to one aspect of the invention, per independent Claim 1, a system for determining a fault condition in an infusion system that provides a primary infusion and a secondary infusion is disclosed (paragraphs [00037]-[00049] and FIGS. 1-3). The infusion system includes an infusion pump (infusion pump set-up 10, paragraph [00037] and FIG. 1) capable of infusing fluid from a primary container (fluid source 14, paragraph [00037] and FIG. 1) connected to a primary infusion line (fluid line 16, paragraph [00037] and FIG. 1), and a secondary container (secondary fluid container 25, paragraph [00038] and FIG. 1) connected to the primary infusion line through a secondary infusion line (secondary fluid line 26, paragraph [00038] and FIG. 1). The secondary infusion line has a valve (manually operated valve 28, paragraph [00038] and FIG. 1) to control flow of the secondary fluid in the secondary fluid line. The primary infusion line has a check valve (one-way check valve 29, paragraph [00038] and FIG. 1) disposed between the primary container and the connection of the secondary infusion line to the primary infusion line. The check valve prevents flow backwards from the primary infusion line into the primary container (paragraph [00038] and FIG. 1).

The system includes a pressure sensor (upstream pressure sensor 50, paragraph [00040] and FIG. 2, and upstream pressure sensor 105, paragraph [00045] and FIG. 3), a memory (memory 80, paragraphs [00042], [00049], and FIG. 3), and a processor (microprocessor 75, paragraphs [00042], [00045], and FIG. 3). The pressure sensor is disposed adjacent to the primary infusion line below the connection of the secondary infusion line to the primary infusion line (paragraphs [00039], [00040], [00045], and FIG. 2). The pressure sensor is in an operative arrangement with the primary infusion line to measure pressure within the primary infusion line

(paragraph [00045] and FIG. 2). The pressure sensor provides signals representative of the pressure within the primary infusion line (paragraph [00045] and FIG. 2). The memory stores pressure related values (paragraph [00049] and FIG. 3). The processor is in communication with the memory and is responsive to the signals provided by the pressure sensor to determine the status of the primary infusion and the secondary infusion (paragraphs [00049], [00051], and FIGS. 2-3). The processor is programmed to sample the pressure signals, establish a baseline pressure value, store the baseline pressure value in the memory, and compare the baseline pressure value with pressure values sampled at a latter time (paragraph [00051] and FIG. 4). If the latter sampled pressure value equals or is greater than a selected threshold pressure value, the processor provides an alert that a fault condition exists (paragraph [00051] and FIG. 4).

According to another aspect of the invention, per independent Claim 8, a system for determining a fault condition in an infusion system providing a primary infusion and a secondary infusion is disclosed (paragraphs [00037]-[00049] and FIGS. 1-3). The infusion system includes an infusion pump (infusion pump set-up 10, paragraph [00037] and FIG. 1) capable of infusing fluid from a primary container (fluid source 14, paragraph [00037] and FIG. 1) connected to a primary infusion line (fluid line 16, paragraph [00037] and FIG. 1), and a secondary container (secondary fluid container 25, paragraph [00038] and FIG. 1) connected to the primary infusion line through a secondary infusion line (secondary fluid line 26, paragraph [00038] and FIG. 1). The secondary infusion line has a valve (manually operated valve 28, paragraph [00038] and FIG. 1) to control flow of the secondary fluid in the secondary fluid line. The primary infusion line has a check valve (one-way check valve 29, paragraph [00038] and FIG. 1) disposed between the primary container and the connection of the secondary infusion line to the primary infusion line. The check valve prevents flow backwards from the primary infusion line into the

primary container (paragraph [00038] and FIG. 1).

The system includes a pressure sensor (upstream pressure sensor 50, paragraph [00040] and FIG. 2, and upstream pressure sensor 105, paragraph [00045] and FIG. 3), a memory (memory 80, paragraphs [00042], [00049], and FIG. 3), and a processor (microprocessor 75, paragraphs [00042], [00045], and FIG. 3). The pressure sensor is disposed adjacent to the primary infusion line below the connection of the secondary infusion line to the primary infusion line (paragraphs [00039], [00040], [00045], and FIG. 2). The pressure sensor is in an operative arrangement with the primary infusion line to measure pressure within the primary infusion line (paragraph [00045] and FIG. 2). The pressure sensor provides signals representative of the pressure within the primary infusion line (paragraph [00045] and FIG. 2). The memory stores pressure related values (paragraph [00049] and FIG. 3). The processor is in communication with the memory and is responsive to the signals provided by the pressure sensor to determine the status of the primary infusion and the secondary infusion (paragraphs [00049], [00051], and FIGS. 2-3). The processor is programmed to sample the pressure signals, establish a baseline pressure value, store the baseline pressure value in the memory, operate the infusion pump to increase the pressure in the primary infusion line, sample the pressure signals after operating the pump to increase the pressure in the primary infusion line, and compare the baseline pressure value with pressure values sampled after operating the pump to increase the pressure in the primary infusion line (paragraphs [00051], [0057] and FIG. 4). If the latter sampled pressure value equals or is greater than a selected threshold pressure value, the processor provides an alert that a fault condition exists (paragraph [00051] and FIG. 4).

According to a further aspect of the invention, per independent Claim 16, a method for determining the status of a secondary infusion is disclosed (paragraphs [00052]-[0059] and FIG.

5). The method includes sampling pressure signals provided by a pressure sensor in operable communication with an upstream infusion line (box 502, paragraph [00052] and FIG. 5), and establishing a baseline pressure from the sampled pressure signals (paragraph [00052] and FIG. 5). The method also includes storing the baseline pressure in a memory (box 504, paragraph [00052] and FIG. 5), causing an increase in the pressure within the upstream infusion line (paragraph [00057]), and sampling the pressure signals after the pressure in the primary infusion line is increased (paragraph [00057]). The method further includes comparing a characteristic of the pressure signals sampled after the pressure in the primary infusion line is increased with a characteristic of the threshold pressure (paragraph [00057]), and providing an alert if the characteristic of the pressure signals is greater than or equal to the characteristic of the threshold pressure (paragraph [00057]).

VI. GROUNDS OF REJECTION TO BE REVIEWED BY APPEAL

1. Whether Claims 1-11 and 16-19 are unpatentable under 35 U.S.C. § 103(a) over U.S. Pat. No. 6,213,972 to Butterfield et al. ("Butterfield") in view of U.S. Pat. No. 5,032,112 to Fairchild et al. ("Fairchild") and U.S. Pat. No. 5,087,245 to Doan ("Doan").

VII. ARGUMENT

1. Rejection under § 103(a) over Butterfield, Fairchild and Doan

Claim 1

The Examiner's Position:

With regards to independent Claim 1, the Examiner asserts that Butterfield in col.26 l.62 to col.27 l.6 discloses a pressure sensor, pressure sensor 34a in FIG. 17, that is disposed adjacent a primary infusion line, conduit 12a, below the connection of a secondary infusion line to conduit 12a, and that pressure sensor 34a is in an operative arrangement with conduit 12a to measure pressure within conduit 12a. Office Action dated April 21, 2008, p.3. The Examiner contends that this teaches Appellants' claimed limitation of "a pressure sensor disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, the pressure sensor in operative arrangement with the primary infusion line to measure pressure within the primary infusion line." *See Id.*

Appellants' Position:

Butterfield does not teach or suggest a pressure sensor disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line as recited in independent Claim 1, let alone a pressure sensor that is both (1) disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, and (2) in operative arrangement with the primary infusion line to measure pressure within the primary infusion line.

Butterfield does not disclose or even suggest that pressure sensor 34a disposed adjacent to the contended primary infusion line, conduit 12a, is below the connection of a secondary infusion line. Quite the contrary, and as is clearly illustrated in FIG. 17 of Butterfield, Butterfield illustrates pressure sensor 34a connected to conduit 12a above, not below, the merging of conduit 12a with conduit 12b. Notably, while the Examiner contends that conduit 12a of Butterfield discloses Appellants' claimed primary infusion line, the Examiner does not even mention what, if anything, in Butterfield discloses Appellants' secondary infusion line. Accordingly, Butterfield does not teach or even suggest a pressure sensor disposed adjacent a primary infusion line below the connection of a secondary infusion line to the primary infusion line.

Furthermore, due to the connection of pressure sensor 34a above the merging of conduits 12a and 12b, pressure sensor 34a of Butterfield is only used to determine the pressure of primary conduit 12a, and not determine a change in pressure of primary conduit 12a caused by a change in pressure within a secondary infusion line. Further, the Examiner has not shown how such an arrangement could determine a change in pressure of primary conduit 12a caused by a change in pressure within a secondary infusion line. Accordingly, Butterfield does not teach or even suggest a pressure sensor that is both disposed adjacent a primary infusion line below the connection of a secondary infusion line to the primary infusion line, and in operative arrangement with the primary infusion line to measure pressure within the primary infusion line.

The remaining references, Fairchild and Doan, are also not seen to teach or suggest a pressure sensor that is both disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, and in operative arrangement with the primary infusion line to measure pressure within the primary infusion line. The Examiner

likewise does not contend that Fairchild or Doan teach or suggest these elements. Fairchild relates to a dual source intravenous administration set having an intravenous pump. Doan relates to a system and method for detecting abnormalities in intravascular infusion. The Examiner has further not identified any suggestion or motivation to modify Fairchild, Doan, or Butterfield to include a pressure sensor that is both disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, and in operative arrangement with the primary infusion line to measure pressure within the primary infusion line.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03; *see also In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). As discussed above, the Examiner has not established that any of the cited references teach or suggest a pressure sensor that is both disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, and in operative arrangement with the primary infusion line to measure pressure within the primary infusion line as recited in independent Claim 1.

Appellants' disclosure provides the only teaching of a pressure sensor that is both disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, and in operative arrangement with the primary infusion line to measure pressure within the primary infusion line. However, the teaching or suggestion to make a claimed combination and the reasonable expectation of success must not be based on Appellants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Accordingly, a *prima facie* case of obviousness of Claim 1 has not been established.

Claim 8

As discussed above with reference to independent Claim 1, the Examiner has not shown that Butterfield teaches or suggests "a pressure sensor disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, the pressure sensor in operative arrangement with the primary infusion line to measure pressure within the primary infusion line," as recited in independent Claim 8. Accordingly, *prima facie* obviousness of independent Claim 8 has not been established by the Examiner.

Claim 16

As discussed above with reference to independent Claim 1, due to the connection of Butterfield's pressure sensor 34a above the merging of conduits 12a and 12b, pressure sensor 34a is only used to determine the pressure of primary conduit 12a and not to determine the pressure of a downstream secondary infusion. Therefore, if there were, for example, an increase in pressure in a primary infusion, such as conduit 12a, pressure sensor 34a of Butterfield could not determine the status, e.g., resulting effect in pressure, of a secondary infusion.

For the same reasons, Butterfield could therefore not teach or suggest a method for determining the status of a secondary infusion that includes causing an increase in the pressure within an upstream infusion line, and sampling the pressure signals after the pressure in a primary infusion line is increased. Accordingly, *prima facie* obviousness of independent Claim 16 has not been established by the Examiner.

Claims 2-7, 9-11, and 17-19

As discussed above, the Examiner has not established a *prima facie* case of obviousness of independent Claims 1, 8, and 16. Claims 2-7, 9-11, and 17-19 depend from independent Claims 1, 8, and 16. Consequently, a *prima facie* case of obviousness of Claims 2-7, 9-11, and 17-19 has not been established for at least the reasons set forth above with respect to independent Claims 1, 8, and 16.

VIII. CONCLUSION

Based upon the arguments submitted above, Appellants respectfully submit that the Examiner's rejection under 35 U.S.C. § 103 is not legally viable. Appellants, therefore, respectfully solicit the Honorable Board to reverse the Examiner's rejection of Claims 1-11 and 16-19 under 35 U.S.C. § 103.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously Presented) A system for determining a fault condition in an infusion system providing a primary infusion and a secondary infusion, the infusion system including an infusion pump capable of infusing fluid from a primary container connected to a primary infusion line and a secondary container connected to the primary infusion line through a secondary infusion line, the secondary infusion line having a valve to control flow of the secondary fluid in the secondary fluid line, the primary infusion line having a check valve disposed between the primary container and the connection of the secondary infusion line to the primary infusion line, the check valve for prevent flow backwards from the primary infusion line into the primary container, comprising:

a pressure sensor disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, the pressure sensor in operative arrangement with the primary infusion line to measure pressure within the primary infusion line, the pressure sensor providing signals representative of the pressure within the primary infusion line;

a memory for storing pressure related values;

a processor in communication with the memory and responsive to the signals provided by the pressure sensor to determine the status of the primary infusion and the secondary infusion, the processor programmed to sample the pressure signals, establish a baseline pressure value, store the baseline pressure value in the memory, compare the baseline pressure value with pressure values sampled at a latter time, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists.

2. (Original) The system of claim 1 wherein the processor determines if the time of the latter

sampled pressure value is within a measurement window before comparing the latter sampled pressure value to the threshold pressure value.

3. (Original) The system of claim 2 wherein the measurement window has a start boundary and an end boundary, and if the latter sampled pressure value has been sampled at a time within the start and end boundaries, and the latter sampled pressure value is equal to or greater than the selected pressure value, the alert is provided.

4. (Original) The system of claim 1 wherein the processor is further programmed to operate the infusion pump in a reverse mode to inject a bolus of fluid into the primary infusion line after establishing the baseline pressure value.

5. (Original) The system of claim 1 wherein the processor is programmed to operate the infusion pump in a reverse mode to inject a bolus of fluid into the primary infusion line if the latter sampled pressure value is less than the selected threshold pressure value.

6. (Original) The system of claim 5 wherein the processor is programmed to sample the pressure signals received from the pressure sensor after operating the infusion pump in the reverse mode, and analyze the pressure signals to determine a characteristic of a pressure wave represented by the pressure signals, and compare that characteristic with a baseline characteristic of the stored baseline pressure value, and if the characteristic is equal to or greater than a selected threshold, provide an alert indicating that a fault condition exists.

7. (Original) The system of claim 6 wherein if the characteristic is less than the selected threshold, provide a check set up alert to a care-giver.

8. (Previously Presented) A system for determining a fault condition in an infusion system providing a primary infusion and a secondary infusion, the infusion system including an infusion pump capable of infusing fluid from a primary container connected to a primary infusion

line and a secondary container connected to the primary infusion line through a secondary infusion line, the secondary infusion line having a valve to control flow of the secondary fluid in the secondary fluid line, the primary infusion line having a check valve disposed between the primary container and the connection of the secondary infusion line to the primary infusion line, the check valve for prevent flow backwards from the primary infusion line into the primary container, comprising:

a pressure sensor disposed adjacent the primary infusion line below the connection of the secondary infusion line to the primary infusion line, the pressure sensor in operative arrangement with the primary infusion line to measure pressure within the primary infusion line, the pressure sensor providing signals representative of the pressure within the primary infusion line;

a memory for storing pressure related values;

a processor in communication with the memory and responsive to the signals provided by the pressure sensor to determine the status of the primary infusion and the secondary infusion, the processor programmed to sample the pressure signals, establish a baseline pressure value, store the baseline pressure value in the memory, operate the infusion pump to increase the pressure in the primary infusion line, sample the pressure signals after operating the pump to increase the pressure in the primary infusion line, compare the baseline pressure value with pressure values sampled after operating the pump to increase the pressure in the primary infusion line, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists.

9. (Original) The system of claim 8 wherein the processor operates the pump in a reverse

mode to increase the pressure in the primary infusion line.

10. (Previously Presented) The system of claim 9 further comprising a controllable pressure application device for applying pressure to the primary infusion line, the pressure application device disposed between an intake of the infusion pump and the connector connecting the secondary infusion line to the primary infusion line.

11. (Previously Presented) The system of claim 10 wherein the pressure application device is responsive to signals from the processor to apply pressure to the primary infusion line.

12-15. (Canceled)

16. (Original) A method for determining the status of a secondary infusion; comprising:

sampling pressure signals provided by a pressure sensor in operable communication with an upstream infusion line;

establishing a baseline pressure from the sampled pressure signals;

storing the baseline pressure in a memory;

causing an increase in the pressure within the upstream infusion line;

sampling the pressure signals after the pressure in the primary infusion line is increased;

comparing a characteristic of the pressure signals sampled after the pressure in the primary infusion line is increased with a characteristic of the threshold pressure; and

providing an alert if the characteristic of the pressure signals is greater than or equal to the characteristic of the threshold pressure.

17. (Original) The method of claim 16 wherein causing an increase in the pressure within the upstream infusion line includes operating an infusion pump in a reverse mode.

18. (Original) The method of claim 16 wherein causing an increase in the pressure within the upstream infusion line includes controlling a device to increase the pressure within the upstream infusion line.

19. (Original) The method of claim 18 wherein the device is an electromechanical actuator and increasing the pressure within the upstream infusion line includes controlling the electromechanical actuator to squeeze and release the upstream infusion line.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

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